

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203049Orig1s000

ENVIRONMENTAL ASSESSMENT

NDA 203-049
Argatroban Injection

Environmental Assessment

A categorical exclusion is claimed for this NDA in accordance with 21 CFR part 21.31 (a). The environmental assessment is justified and acceptable per Li Shan Hsieh on pages 46-49 of the CMC review dated December 1, 2011.